

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 6, 19, and 21 are amended to correct clerical errors in the claims. The amendments do not raise any new issues and are not intended to alter the scope of the claims. Claims 1-21 are presented for reconsideration.

Claim Rejections – 35 U.S.C. § 103

Claims 1-21 stand rejected as allegedly obvious over U.S. Patent No. 5,656,286 to Miranda *et al.* and U.S. Patent No. 5,474,783 to Miranda *et al.* in further view of U.S. Patent No. 5,230,898 to Horstmann *et al.* Applicants respectfully traverse the rejection.

According to the Office Action, the '286 patent teaches a blend of at least two polymers in combination with a drug for formulating a transdermal delivery composition. As recognized at page 4 of the Office Action, the '286 patent does not teach a transdermal composition comprising polymers with the characteristics recited in the instant claims. Although the Office Action also cites the '783 and '898 patents, that combination of references does not suggest the present invention.

The '783 patent discloses a transdermal composition comprising Bio-PSA X7-3027 and Duro-Tak 80-1194. According to the Office Action, the '783 patent further teaches that these polymers can be used to form compositions, which retain acceptable shear, tack and peel properties. Thus, the Office Action concludes that a skilled artisan "would be motivated to use different polymers [*sic*] combinations, drug (e.g. nicotine) in place of the nitroglycerine used by [the '783 patent] in amounts that would produce a dermal formulation that has pressure sensitive adhesive properties and shear resistance as claimed by applicant." Office Action at 4.

The '898 patent is cited to show a transdermal drug delivery composition comprising basic polymers, such as polyacrylic acid ester, and nicotine, which exhibits pressure-sensitive adhesive properties. According to the Office Action, a skilled artisan would be motivated by this disclosure "to use different combinations of polymers and drugs that give formulations with desirable shear, tack and peel characteristics as claimed by applicant." Office Action at 4.

B. The Claimed Invention Is Not Obvious Over The References of Record

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As discussed below, the Examiner has failed to meet this burden necessary to establish a *prima facie* case of obviousness.

1. There Is No Motivation To Combine The References

Each of the references of record focuses on a problem different from that addressed by the present invention. The '286 patent discloses polymer compositions comprising polyvinylpyrrolidone, which are shown to be useful to prevent drug crystallization without affecting the rate of drug delivery. The '783 patent discloses a method of adjusting saturation concentration of a drug in a transdermal polymer composition comprising mixing polymers with different solubility parameters. Finally, the '898 patent discloses a transdermal therapeutic system with a specific arrangement of layers. None of the references address the problem solved by the present invention, which addresses the tendency of low molecular weight drugs that are

liquid at room temperature to plasticize polymer matrices, thereby making it difficult to formulate suitable transdermal patches comprising such drugs. *See, e.g.*, EP 0 887 075 A2 to Govil *et al.* It is only the present invention that teaches the use of the recited high shear resistant acrylic-based polymers in order to address the problems caused by low molecular weight drugs. Thus, the present invention satisfies a long-felt need in the art that has heretofore not been solved. Moreover, none of the references teach or suggest a transdermal system comprising a high shear resistance acrylic-based polymer and a low molecular weight drug that is liquid at or about room temperatures.

2. *Motivation Based On Hindsight Is Impermissible*

The Office Action asserts that a skilled artisan would be motivated to “use different polymers [and] drug ... [to] produce a dermal formulation that has pressure sensitive adhesive properties and shear resistance as claimed by applicant.” Office action at 4. However, “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” MPEP § 2143.01 (citations omitted). Here, where the claimed references do not teach or suggest the desirability of the claimed combination, the obviousness rejection is improper. *See Ex parte Levengood*, 28 USPQ2d 1300 (BPAI 1993) (reversing an obviousness rejection because the prior art evinced no understanding in the art that would have motivated the skilled artisan to make the claimed invention). Indeed, the references of record are silent on the benefits of using “high shear resistant acrylic-based polymer” in combination with drugs, which are “low molecular weight and liquid at or about room temperatures,” as presently claimed.

Any motivation to make the claimed invention can only be achieved by impermissible hindsight. A skilled artisan would have to pick and choose particular drugs and polymers from the prior art, but the prior art provides no guidance that would lead to the claimed composition. The only guidance comes from Applicants’ own specification, but the use of the present disclosure to provide motivation to combine the references is impermissible hindsight. MPEP §

2145. Because the prior art itself does not provide motivation to make the claimed invention, the obviousness rejection is improper and should be withdrawn.

3. *The Polymers Cited by the Examiner Do Not Have the Recited Characteristics*

The Office Action argues that the '286 patent discloses the use of polymers "having shear resistance of 100 and above at 8lbs/sq in at 72 degrees F." As examples, the Office Action lists polymethylacrylate (col. 8, Table 1A), Bio-PSA X-7-4503, and Duro-Tak 80-1196. However, these polymers lack the recited characteristics. The '286 patent is silent on the shear resistance of the polymethylacrylate. Bio-PSA X-7-4503 is not acrylic-based but instead is silicone-based. Finally, Duro-Tak 80-1196 has a shear resistance of only about 15 hrs. at 8 lbs. per square inch at 72°F. Thus, the polymers do not have the characteristics of the polymers recited in the instant claims, and therefore do not support the obviousness rejection.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection against claims 1-21.

CONCLUSION

Applicants believe that the present application is now in condition for allowance, and an early notice to that effect is earnestly solicited.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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